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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,531	12/22/2003	Timothy P. Mate	341148004US3	7678
69414 7590 08/18/2008 CALYPSO MEDICAL / PERKINS COIE, LLP P.O. BOX 1247 SEATTLE, WA 98111-1247				
EXAMINER				
ROZANSKI, MICHAEL T				
ART UNIT		PAPER NUMBER		
3768				
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08/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/743,531

**Applicant(s)**

MATE ET AL.

**Examiner**

MICHAEL ROZANSKI

**Art Unit**

3768

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 144-150 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 144-150 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 144-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Vilsmeier et al*** (US 6,611,700) in view of ***Doron et al*** (US 6,239,724).

Vilsmeier et al disclose a method and apparatus for positioning a patient 1 lying on a bench 9 for radiation treatment. The patient is positioned such that the isocenter 3 is located in the center of the tumor 2 to be irradiated. A glass fiber cable 6, which serves as a position sensor, is attached to a controller 8 so that the position and directional vector of the outgoing glass fiber 6 is clearly defined by a connecting point serving as a fiducial point to permit obtaining information regarding the location of the glass fiber 6 as a whole using this fiducial point. The other end of the cable 6 is implanted in the patient body 1 and fixed in the site of the tumor 2, the end point 4 of the cable 6 not being located on the tumor. By using the positional information of the cable 6 established by the controller 8, the absolute momentary position of the tumor 2 can be detected by determining the position of the end point 4 and/or of a further optional point 5 on the cable. The controller detects the three-dimensional position of individual points 4, 5 and is then able to determine whether the tumor 2 is in the permitted site

circumscribing the isocenter and to suitably control the patient bench 9 to position the tumor 2 and/or the radiation source accordingly. The radiation source turns OFF when the tumor 2 moves out of the isocenter 3 and back ON when tumor 2 is in the isocenter 3 (col 4, line 56-col 5, line 26). The controller 8 is a device that loads and executes computer program code and, therefore, is a computer including computer operable instructions. In addition, the controller 8 repeatedly receives positional information of the individual points 4, 5, determines a location of the marker relative to a frame of reference defined by positional information of the glass fiber cable 6, and computes a displacement between the location of the marker and a desired location of the marker wherein the target is located at a desired situs in the reference frame when the marker is at the desired location for the marker (see col 5, lines 17-26). This also indicates that the bench 9 is moved according to the actual location of the target if a displacement between the actual location of the target and a desired location for the target is beyond an acceptable range.

Vilsmeier et al disclose that the position sensor is a glass fiber cable, thereby not transmitting information wirelessly. However, Vilsmeier et al also states that in principle, any sensor may be used as the position sensor enabling the three-dimensional location (col 2, lines 16-19). Doron et al teaches of a system and method used to position a medical instrument and/or direct a medical procedure within a patient's body, such as a therapeutic radiation treatment. System 100 provides spatial positioning information from within a patient's body including an implantable telemetry unit 102 for wirelessly transmitting information from inside the body to extracorporeal unit 116 located outside

the body for analysis (col 8, lines 18-60; see figure 1). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify Vilsmeier et al to include a wireless marker, as taught by Doron et al, because Vilsmeier teaches that alternate sensors capable of providing three dimensional information are suitable for use in their arrangement and Doron et al teaches one such arrangement. For example, a wireless sensor may be used because the use of wire connections prevents the use of this design in intracranial applications, may serve as potential conduits for infection, cannot be left inside the body for long periods of time, and can result in loss of positioning information if the wire breaks (col 3, line 60-col 4, line 9).

In regard to claims 148-150, Vilsmeier et al disclose that the controller 8 receives information regarding the absolute momentary position of the tumor, but do not teach that this information is stored or sent to a memory. However, it is well established in the art that many computers and controllers have data storage capabilities. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify Vilsmeier et al to include a memory with the controller in order to store information regarding the desired target site to help move the patient for initial alignments with the beam isocenter.

### ***Response to Arguments***

Applicant's arguments filed 5/29/08 have been fully considered but they are not persuasive. Applicant argues that the telemetry system of Doron cannot be combined with the teachings of Vilsmeier to yield the claimed invention because Vilsmeier teaches

that a curvature of a flexible position sensor is detected along the sensor length. However, Examiner finds that Vilsmeier describes a system that is utilized with a position sensor that outputs signals indicating its position from which its three-dimensional location can be definitely determined, for example, the specific point of the sensor in space to be clearly determined (col 2, lines 12-19). Vilsmeier goes on to describe one possible sensor type (flexible cable or tape-type sensors) that could be used to determine three-dimensional location (col 2, lines 20-28). A curvature is detected, which involves determining the location of several points. It is not found in Vilsmeier that a sensor of the flexible cable or tape-type is the only type of position sensor that can be used. Rather, another sensor such as the one disclosed by Doron et al could be used because it meets the requirements set forth in Vilsmeier, namely outputting signals indicating its three-dimensional position from a specific point or several points (col 5, line 1). Therefore, Applicant's assertion that only cable-type sensors can be used is not found persuasive because the cable sensor is only one type of sensor, wherein such a sensor would detect the curvature by detecting several points. Furthermore, one of ordinary skill in the art would recognize that other types of sensors such as a wireless sensor that does not detect curvature may be configured to operate according to Vilsmeier.

Applicant also argues that Doron fails to provide a motivation for replacing the flexible position sensor of Vilsmeier with the telemetry system of Doron. However, Examiner asserts that the motivation is found in Vilsmeier, and thus, need not be

additionally provided by Doron (although as given in the statement of the rejection, Doron does have relevant teachings/motivations).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

MR